

CERTIFICATE OF REGISTRATION

This is to certify that the management system of:

Orthomerica Products, Inc.

(FIN F001562)

Main Site: 6333 N. Orange Blossom Trail

Orlando, FL, 32810, USA

has been registered by Intertek, an MDSAP recognized auditing organization,
as conforming to the requirements of:

ISO 13485:2016

Australia: Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6)

Brazil: Federal Law n. 6360/76; RDC ANVISA n. 16/2013; RDC ANVISA n. 23/2012; RDC ANVISA n. 67/2009; RDC ANVISA n. 56/2001

Canada: Medical Devices Regulations – Part 1- SOR 98/282

United States: 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 (Subparts A to D)

Japan: MHLW Ministerial Ordinance 169, Article 4 to Article 68; PMD Act

The management system is applicable to:

Design, development, and manufacture of prefabricated, custom-to-measurement, and custom-to-cast orthopedic orthoses. Installation of laser data acquisition system for orthopedic orthoses.

Certificate Number:

0087702

Initial Certification Date:

2019-02-28

Certification Effective Date:

2019-02-28

Certification Expiry Date:

2022-02-27



Calin Moldoveanu

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